



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 27, 2020

Jennifer Brandon
Agent
CR Brands, Inc.
c/o Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Volcano
EPA Registration Number: 95337-1
Application Date: April 2, 2020
Decision Number: 561469

Dear Ms. Brandon:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

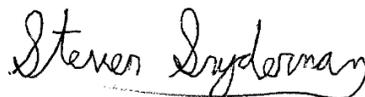
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus type 37 and/or Rotavirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

VOLCANO

[Alternate Brand Name: Arm & Hammer Essentials Disinfecting Wipes]

ACTIVE INGREDIENT

Citric Acid1.5%

OTHER INGREDIENTS98.5%

TOTAL100.0%

CAUTION

KEEP OUT OF REACH OF CHILDREN

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center 1-800-222-1222. For general information on this product, call the National Pesticides Information Center 1-800-858-7378 Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu .	

[First aid may be in paragraph format]

[See [side] [back] panel for [additional] [precautions] [precautionary statements]]

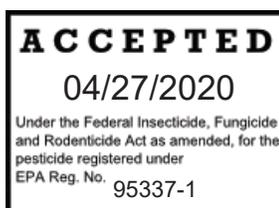
[Manufactured] [Distributed] [by] [for]:

CR Brands, Inc.
8790 Beckett Rd
West Chester, OH 45069

EPA Reg. No.: 95337-1

EPA Est. No.:

NET CONTENTS [*and/or Net Weight*]: _____
[*Insert number*] [Cloths] [Wipes] [Towelettes] [*Size of each towelette*]



[Text in brackets is optional; Text in brackets and italicized is instructional]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

STORAGE AND DISPOSAL

Storage: Keep lid closed when not in use. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in trash. Do not flush. **Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or place in trash.

ORGANISMS

[ATCC numbers are not required to be listed on production label. Organisms may be listed in a table and in any order.]

[Disinfection] [5 minutes contact time]

[Bactericidal] [Germicidal] [This product has demonstrated efficacy against:]

[*Staphylococcus aureus* [ATCC 6538]]

[*Salmonella enterica* [ATCC 10708]]

[*Escherichia coli* [ATCC 11229]]

[*Methicillin resistant staphylococcus aureus* [ATCC 33592]]

[*Streptococcus pyogenes* [ATCC 19615]]

[Virucidal] [This product has demonstrated efficacy against:]

[Human coronavirus [ATCC VR-740]]

[Influenza H1N1 [ATCC VR-1469]]

[Rhinovirus Type 37 [ATCC VR-1147]]

[Rotavirus [ATCC VR-2018]]

[Non-food contact sanitizer] [5 minutes contact time]

[*Staphylococcus aureus* [ATCC 6538]]

[*Klebsiella pneumoniae* [ATCC 4352]]

Dispenser [Canister] Directions [Instructions]:

1. Pull wipe from center of roll and feed into opening
2. Next sheet will automatically feed through opening
3. Firmly close lid to avoid dry-out and retain moisture

[or]

1. Open lid and remove seal
2. Pull out wipe from center of opening
3. Push excess wipes back into pack
4. Firmly close lid to avoid dry-out and retain moisture

[Text in brackets is optional; Text in brackets and italicized is instructional]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PRE-CLEANING: Required prior to disinfection and sanitization. Unfold a wipe. Wipe until clean.

TO DISINFECT [AND DEODORIZE] hard nonporous surfaces: To disinfect, unfold clean wipe and thoroughly wet surface. Allow surface to remain wet for *[or]* [The surface must remain wet for at least] *[or]* [Leave wet for] five [5] minutes. [Use additional wipe(s) if needed to assure surface remains wet]. Let air dry. A potable water rinse is required for food contact surfaces.

TO SANITIZE [AND DEODORIZE] hard nonporous nonfood contact surfaces: To sanitize and deodorize, unfold clean wipe and thoroughly wet surface. Allow surface to remain wet for *[or]* [The surface must remain wet for at least] *[or]* [Leave wet for] five [5] minutes. [Use additional wipe(s) if needed to assure surface remains wet]. Let air dry.

[AREAS OF USE:]

[Claims may appear on front, side or back panels of packaging or marketing materials in bullet or paragraph format; choose one or more areas of use]

For use on hard nonporous surfaces of [kitchens], [bathrooms], [offices], [schools], [classrooms], [playrooms], [daycares], [pet areas], [veterinary clinics], [laundry rooms], [dorms], [garage], [cars], [gyms]

For use on [computers/keyboards], [doorknobs], [exercise equipment], [coolers], [floors], [trash cans], [changing tables], [diaper pails], [pet crates]

For use on [stainless steel], [sealed granite], [finished hardwood], [tubs & [and] shower walls], [toilet exteriors], [hard nonporous surfaces of car interiors]

Great for use on hard nonporous surfaces of [kitchens], [bathrooms], [offices], [schools], [classrooms], [playrooms], [daycares], [pet areas], [veterinary clinics], [laundry rooms], [dorms], [garage], [cars], [gyms]

Great for [use on] [computers/keyboards], [doorknobs], [exercise equipment], [coolers], [floors], [trash cans], [changing tables], [diaper pails], [pet crates]

Great for [use on] [stainless steel], [sealed granite], [finished hardwood], [tubs & [and] shower walls], [toilet exteriors], [hard nonporous surfaces of car interiors]

Worry-free use on [computers/keyboards], [doorknobs], [exercise equipment], [coolers], [floors], [trash cans], [changing tables], [diaper pails], [pet crates]

Worry-free use on [stainless steel], [sealed granite], [finished hardwood], [tubs & [and] shower walls], [toilet exteriors], [hard nonporous surfaces of car interiors]

[TYPES OF SURFACES:] [USE SITES:]

[Claims may appear on front, side or back panels of packaging or marketing materials in bullet or paragraph format; choose one or more surface types]

[The following statement is intended to provide users with information on where the product can be used]

Safe [Intended] for use on [stainless steel] [sealed granite] [finished hardwood] [tubs & shower walls] [toilet exterior] [hard nonporous surfaces of car interiors]

[Test a small area first]

[Text in brackets is optional; Text in brackets and italicized is instructional]

[OPTIONAL ANTIMICROBIAL CLAIMS]

Citrus-based Disinfection
Disinfectant Wipe(s)
Disinfects
Disinfects [common] [household] [kitchen] [and] [bathroom] bacteria
 [including:] *[list organisms from the organism list]*
Disinfecting Wipe[s]
Effectively controls odors
Eliminates odor-causing bacteria
Eliminates 99.9% [99.999%] of *[Name of Virus/Bacteria]*
Eliminates 99.9% [99.999%] of cold and flu viruses
 [including:] *[list organisms from the organism list]*
Eliminates 99.9% [99.999%] of viruses and bacteria
 [including:] *[list organisms from the organism list]*
Eliminates 99.9% [99.999%] of viruses and bacteria in 5 minutes
 [including:] *[list organisms from the organism list]*
Everyday surface disinfectant
Kills [Effective against] [Destroys] *[Name of Virus/Bacteria]*
Kills [Eliminates] [Effective against] [Destroys] 99.9% [99.999%] of germs*
 *[Back Panel:] *Kills [list organisms from the organism list]*
Kills [Eliminates] [Effective against] [Destroys] 99.9% [99.999%] of viruses and bacteria
 [including:] *[list organisms from the organism list]*
Kills [Effective against] [Destroys] cold and flu viruses
 [including:] *[list organisms from the organism list]*
Kills [Effective against] [Destroys] viruses and bacteria
 [including:] *[list organisms from the organism list]*
Kills [Effective against] [Destroys] viruses and bacteria in 5 minutes
 [including:] *[list organisms from the organism list]*
Kills [Eliminates] [Effective against] [Destroys] 99.9% [99.999%] of viruses and bacteria including cold and
 flu viruses
Sanitizes [hard nonporous surfaces] in 5 minutes
Tough on [dirt] [and] [germs]
Wipe(s) away [dirt] [and] [germs]

[OPTIONAL NON PESTICIDAL CLAIMS]

Bleach-free *[this is included as useful information for users needing a bleach-free product]*
Botanical
Botanical active Ingredient
Botanical cleaning
Botanically derived active ingredient
Botanically derived ingredient(s)
Botanically-based [product]
[Can be used] around kids and pets
Cleans #x better (vs. a wet paper towel)
Cleans without [harsh] *[or]* [strong] chemical(s)
Does not contain [bleach] *[or]* [ammonia] *[or]* [chlorine] *[this is included as useful information for users
needing a bleach / ammonia free product]*
Does not contain [Triclosan] *[or]* [Paraben] *[this is included as useful information for users needing a
triclosan or paraben free product]*

[Text in brackets is optional; Text in brackets and italicized is instructional]

Dye free *[this is included as useful information for users needing a dye-free product]*
Effective cleaning
Everyday cleaner
Free from alkyl dimethyl benzyl ammonium chloride *[this is included as useful information for users needing a quat-free product]*
Free from ammonia *[this is included as useful information for users needing an ammonia free product]*
Free from bleach *[this is included as useful information for users needing a bleach-free product]*
Multi-purpose cleaner
No alkyl dimethyl benzyl ammonium chloride
No ammonia *[this is included as useful information for users needing an ammonia free product]*
No bleach *[this is included as useful information for users needing a bleach-free product]*
No gloves required
No quaternary ammonium compounds* (* alkyl dimethyl benzyl ammonium chloride) *[this is included as useful information for users needing a quat-free product]*
Non-corrosive
Non-irritating to skin
Paraben free
Phenol free
Powerfully pure cleaning
Powers through tough grease and grime
Pure and simple cleaning
Quick & easy cleaning
Textured wipes for a better clean
Textured wipes for tough cleaning
Worry-free cleaning on *[list type of surface / areas of use]*

[OPTIONAL PACKAGING CLAIMS AND PRODUCT DESCRIPTORS]

% thicker [wipe]
X thicker [wipe]
[Large] [Thick] [&] [Durable] [Wet] Wipes
[Large] [Wet] Wipes
Full-sized Wet Wipes
[Large] [Thick] [&] [Durable] [Wet] Wipes (# x ## count)
[Large] [Wet] Wipes (# x ## count)
Full-sized Wet Wipes (# x ## count)
Wipes (# x ## count)
% Thicker*
 **[vs. Arm & Hammer Essentials™ Disinfecting Wipes]*
x Thicker*
 **[vs. Arm & Hammer Essentials™ Disinfecting Wipes]*
Click-close
Click-close for maximum freshness
Compact size
Dispenses one wipe at a time
Do not flush [in toilet]
Do not use as a diaper wipe or for personal cleansing
Easy Start
Easy to [stack] [and] [store]
Easy to pull

[Text in brackets is optional; Text in brackets and italicized is instructional]

Easy to start and dispense
Easy to take on the go
Easy to use and store
First Wipe is Ready to Use
Freshness guaranteed
Freshness-lock
Freshness-lock lid
Full-size, thick and durable wipes
Ideal for [briefcases] [and] [glove compartments] [and] [purses] [and] [travel] [and] [vehicles]
Ideal for briefcases
Ideal for glove compartments
Ideal for purses
Ideal for travel
Ideal for vehicles
Includes Biodegradable Detergents
Inspired by nature
Large, thick and durable wipes
Locks in moisture to keep wipes fresh
Low streak formula
Moist wipes till the end, guaranteed
Moisture-lock
Moisture-lock lid
Multi-purpose
Multi-surface
No dry-out, guaranteed
No unpleasant [smell] [scent] [odor]
Opens with one hand
Snap-close
Snap-close for maximum freshness
Snap-close lid
Snaps-closed
Soft collapsible packaging that's easier to store [*Claim to be used when using soft collapsible packaging*]
Space saving pack
Stackable
Stay-fresh lid
Stay-fresh, guaranteed
[Take] on the go
Takes up less space than bulky canisters
Thick and durable [wipes]
This is not a baby wipe
Tough wipes; so you can use less to get the job done
Use ##% less plastic than canisters [wipes]
Use ##% less plastic than similar count canisters
Wet-lock [lid]
Wide opening for [easy] easier [wipe] [dispensing] [pull]
Wide opening for easy access to wipes [roll]
Will not damage hard nonporous surfaces [*list type of surface / areas of use*]
Worry-free use on [*list type of surface / areas of use*] [*acceptable images (listed below)*]

[*Text in brackets is optional; Text in brackets and italicized is instructional*]

[Product Sourcing information]

Assembled in the USA of global components *[Claim for when product is manufactured in USA]*

Designed in the USA, responsibly made in Vietnam *[Claim for when product is manufactured in Vietnam]*

Made in the USA *[Claim for when product is manufactured in USA]*

[Scent Names]

A Mist of Rain [Scent]

After the Rain [Scent]

Citrus Medley [Scent]

Citrus Mist [Scent]

Essential Lemon [Scent]

Fresh [Scent]

Fresh Morning Mist [Scent]

Fresh Rain Drops [Scent]

Grapefruit [Scent]

Lemon [Scent]

Lemon Grove [Scent]

Lemon Medley [Scent]

Lemon Mist [Scent]

Lemon Orchard [Scent]

Lemongrass [Scent]

Lemongrass Ginger [Scent]

Meadow Rain [Scent]

Morning Rain [Scent]

Renewing Rain [Scent]

Unscented

[OPTIONAL CLAIMS FOR MULTI & PROMOTION PACKS]

Pack (# = 2, 3, 4 or 5)

More wipes

% bonus pack

% more free

Back-to-school pack

Bonus pack

Promotional pack

Seasonal print

Seasonal scent

Spring cleaning pack

Twin pack

Value pack

[Note: The following claims can be used only for 6 months]

New [wipe] [towelette]

Introducing [new] [wipe] [towelette]

[This item is manufactured, marketed and distributed by CR Brands, Inc. ARM AND HAMMER and the ARM AND HAMMER Logo and distinctive orange trade dress are trademarks of Church & Dwight Co., Inc., and are used by CR Brands, Inc. under license.]

[Questions?] [Comments?] [Go to www.ahcleans.com] [or] [call us at 1-888-334-4890]

[For more product ingredient information, visit ahcleans.com/ingredients]

[Text in brackets is optional; Text in brackets and italicized is instructional]

Emerging Viral Pathogens Claims

[This product qualifies for emerging viral pathogen claims per EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below.]

[This product meets the criteria to make claims against emerging viral pathogens from the following viral categories:]

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an:	...follow the directions for use for the following organism on the label:
Enveloped Virus	Rhinovirus type 37; Rotavirus
Large Non-Enveloped Virus	Rhinovirus type 37

[Statements must adhere to one or both of the following formats:]

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, non-porous surfaces. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus – see table above]** on hard non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus – see table above]** on hard non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

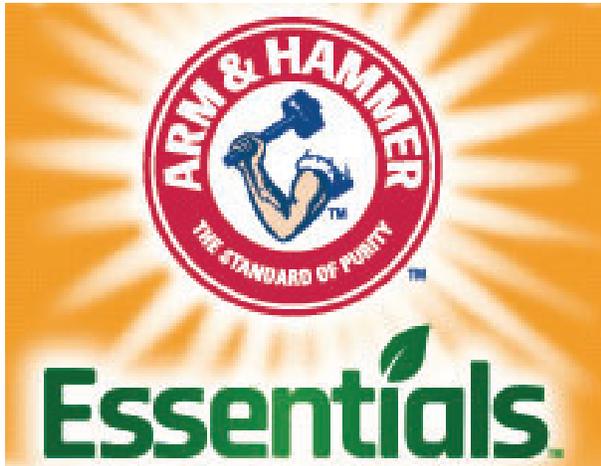
[These statements shall not appear on marketplace (final printed) labels]

OPTIONAL GRAPHICS:

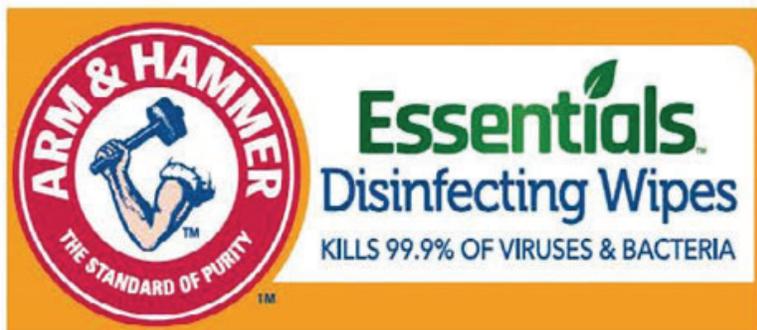




*Food contact surfaces must be rinsed with potable water



[Text in brackets is optional; Text in brackets and italicized is instructional]



**Food contact surfaces must be rinsed with potable water*

[Text in brackets is optional; Text in brackets and italicized is instructional]

[Examples of graphics for fragrances / scents]

